

ANALYSIS CERTIFICATE, REANALYSIS

Summary protocol

ORAL ETEC VACCINE

SV 30046

Lot no: E 003A

Expiry date: 971101

Date of manufacture: June 21, 1994

Quality Control Test	Specification	Test results	Date	Sign
Identity				
ELISA test (Mab)	Reaction with antibodies for CFA/I, CS1, CS2, CS4, CS5	Passed	Apr 15, 1996	FoA/PA
Gram staining	Only Gram negative rods typical of <i>E. coli</i>	Passed	Dec 11, 1996	QC/IMP
Ouchterlony test	Identity with r-CTB and CTB	Passed	Dec 18, 1996	PDT/MFP
Fimbrial antigen content				
ELISA test (Mab)	> 20 µg/dose of each of CFA/I, CS1, CS2, CS4, CS5	Passed	Jan 10, 1997	GBG/GW
r-CTB content				
Mancini test	1.0 ± 0.2 mg/dose	0.76 mg	Dec 13, 1996	PDT/MFP
Sterility	No growth	Passed	Dec 17, 1996	QC/BC
Abnormal toxicity	No death or morbidity	Passed	Jan 8, 1997	QC/AF
Residual formaldehyde	≤ 0.01 M	0.0043 M	Dec 17, 1996	QC/BM
Homogeneity	Homogeneous suspension	Passed	Dec 10, 1996	QC/IMP
pH	6.5 - 7.8	7.1	Dec 17, 1996	QC/BM

Volume/dose: 4.0 ml

Filled volume: 4.2 ml/bottle

Note: The content of r-CTB is at the lowest acceptable value and may fall below specification during the period of use. A retest will be performed August 1997.

The product complies with the specification

Date: 970218

Anders Mählén